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Quality of life in automatic implantable cardioverter defibrillator recipients

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QUALITY OF LIFE IN AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR RECIPIENTS

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By

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ABSTRACT

QUALITY OF LIFE IN AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR RECIPIENTS

by Debra L. Deis

The purpose of this exploratory study was to describe the perceived quality of life of automatic implantable cardioverter defibrillator (AICD) recipients. The Quality of Life Index (QLI) was completed by 37 AICD recipients. Telephone interviews were completed to identify what significant changes occurred as a result of the AICD and who, other than the AICD recipient, was most affected. Correlation coefficients were calculated to determine the relationship between QLI scores and length of time since AICD implantation, and between QLI scores and number of converting shocks delivered to recipients. No relationship was found between any QLI score and length of time since implantation. A low correlation (r = .31) was found between the overall QLI score and number of shocks delivered. A moderate correlation (r = .44) was found between the health and functioning subscale score and number of shocks delivered.

ACKNOWLEDGEMENT

In memory of my father who provided a lifetime of encouragement, love, and support. To my children, Megan and Adam, and to my mother, who gave me the freedom and encouragement to continue my education and write this thesis. To all of those who have crossed my path and have given their support as I journeyed through the process of thesis writing.

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INTRODUCTION

Sudden cardiac death strikes an estimated 300,000-500,000 Americans annually (American Heart Association, 1988). Eighty percent of these patients die without resuscitation, and 20% of those who survive cannot be helped by conventional surgery or antiarrhythmic drug therapy (Moser, Crawford, & Thomas, 1988). Tachyarrhythmia is the major cause of sudden cardiac death (Panidis & Morganroth, 1985).

During the past ten years, major advances have been made in the diagnosis and treatment of tachyarrhythmias associated with sudden cardiac death. One of the most significant advances has been the development of the Automatic Implantable Cardioverter Defibrillator (AICD). The AICD is a device which continuously identifies life threatening dysrhythmias and delivers converting shocks. The expected longevity of the current model AICD is about three years.

In 1980, the first human implant of the AICD was successfully accomplished. Since that time, over 6,800 devices have been implanted in patients with ventricular dysrhythmias resistant to antidysrhythmic agents (Teplitz, Egenes, & Brask, 1990). Once implanted, the device can significantly reduce a cardiac patient's sudden death

mortality rate to less than three percent per year (Moser, Crawford, & Thomas, 1988).

Background of the Problem

The diagnosis of sudden cardiac death and the implantation of the AICD has significant psychological, physical, and financial implications for patients and their families. While the device has made great advances in increasing length of life, little research is available to define the quality of life of AICD recipients.

Dunnington and Finkelmeier (1988) identified common psychological characteristics of the survivors of sudden death. These characteristics included fear, insomnia, anxiety, depression, and restriction of physical activity beyond that recommended by the physician. The surgical scar and abdominal protrusion serve as a constant reminder of a potentially fatal heart condition. As the patient accepts the AICD as a condition of existence, reliance on an electronic mechanism and fear of its malfunction are causes for concern (Teplitz, Egenes, & Brask, 1990). Fear of the cardioverting shock from the defibrillator, with its associated discomfort and potential loss of consciousness, causes a great deal of anxiety. Some patients also fear the embarrassment and pain of receiving a shock in a public place. How these psychological aspects affect the quality

of life of AICD recipients has not been widely described in the literature.

The diagnosis of sudden cardiac death resulting in the implantation of an AICD is associated with numerous physical needs. Many patients require multiple medications to control the potential recurrence of dysrhythmias. Side effects are often severe, and blood testing may be required to maintain adequate control of the drug level. Physician or clinic visits are required every one to two months. During this time the device is "interrogated" to gain information on the status of the device. The closer the device comes to the end of its battery life, the more frequent the clinic visits, until replacement is required.

The recipient's financial security may be threatened following AICD implantation. Lifestyle modifications such as driving restrictions, travel limitations, and potential career changes may result in loss of earnings, independence, and self-esteem. Additionally, patients may fear the need for health care while traveling to a place where personnel are unfamiliar with the device. This may cause disharmony within the family, and lead the patient to isolation from family, friends, and social situations (Teplitz, Egenes, & Brask, 1990).

Statement of the Problem

Patients with an AICD present major issues that relate to their psychological, physical, and economic well-being. It was the researcher's belief that the psychological, physical, and economic changes that occur as a result of AICD implantation affects the quality of life of AICD recipients.

Purpose

The purpose of this research study was to describe the quality of life of Automatic Implantable Cardioverter Defibrillator (AICD) recipients using the Quality of Life Index (QLI). Information gained from this study can be used in the development of strategies to improve quality of life for AICD recipients and their families.

Definition of Terms

For the purpose of this study, the following definitions were used:

1. Automatic implantable cardioverter defibrillator (AICD) is an electronic device implanted in the abdomen of persons with a history of tachyarrhythmias leading to sudden cardiac death. The AICD continuously monitors the heart rhythm through sensing electrodes placed on the heart (Cannom & Winkle, 1986). When the AICD identifies that ventricular fibrillation or ventricular tachycardia has occurred, it defibrillates the heart in an effort to restore

an effective cardiac rhythm. It is capable of continuously monitoring and delivering 100 - 150 shocks during the life of the device.

2. Sudden cardiac death is an unexpected witnessed death of a person with no known illnesses, resulting from cardiac dysfunction and occurring within one hour of the onset of new symptoms (Featherston, 1988). This syndrome does not include persons with a recent acute onset of heart disease, but does include persons diagnosed with coronary artery disease whose conditions are considered stable.

3. Quality of Life is the score obtained by The Quality of Life Index (QLI) by Ferrans and Powers (1984). The QLI was used to measure quality of life in four subscales: Health and functioning, socioeconomic, psychological/spiritual, and family. Conceptually, quality of life was defined as "satisfaction with life, psychosocial as well as physical."

Objectives and Questions

In heart disease, as in other chronic diseases, the primary goal of therapy is to reduce the number of consequences of the illness so that individuals may lead a comfortable and satisfying life. Therefore, this research was designed to meet the following objectives: (a) to explore quality of life issues in automatic implantable cardioverter defibrillator recipients; (b) to generate data

which could be applied to the development of therapeutic modalities, using quality of life as an outcome; and (c) to contribute to the growing body of knowledge on quality of life as it relates to chronic illness.

Based on these objectives the research questions for this study were:

1. What is the perceived quality of life of AICD recipients?

2. What is the relationship between length of time since AICD implantation and quality of life as perceived by AICD recipients?

3. What is the relationship between the number of converting shocks delivered to AICD recipients and their perceived quality of life?

Research Design

This was an exploratory study of the perceived quality of life of Automatic Implantable Cardioverter Defibrillator recipients. Participants approached for this study met the following inclusion criteria: (a) being over 40 years of age; (b) being able to speak, read, and write in English; and (c) having had an AICD implanted for at least one month. Patients with experimental devices were excluded, as were those who had AICD battery replacements.

Quality of life was measured by the Quality of Life Index (QLI) developed by Ferrans and Powers, and copyrighted

in 1984 (see Appendix A). This self-administered questionnaire consisted of two sections, one measuring satisfaction with various domains of life, the other measuring the importance of the domain to the subject. The QLI was used to measure quality of life overall and in four subscales: Health and functioning, socioeconomic, psychological and spiritual, and family. The QLI was mailed to potential subjects a minimum of one month after implantation of an AICD. Following guidelines provided by the instrument's authors, scoring and statistical analysis of the QLI was done on each questionnaire at the end of data collection. As a result, a composite quality of life score was obtained, as well as scores for each of the four subscales, for each subject.

Scope and Limitations

The scope of this study was concerned with describing the quality of life of individuals after the surgical implantation of the AICD in patients with life threatening dysrhythmias. The literature confirms that many difficulties are imposed by the physiologic, sociologic, and psychologic changes of heart disease (Featherston, 1988; Noel, et al., 1986; Dunnington & Finkelmeier, 1988; Miccolo, 1988). These changes are not limited to the patient, but extend to spouses, family members, and friends (Pycha,

Calabrese, Gulledge, & Maloney, 1990; Badger & Morris, 1989; Sirles & Selleck, 1989).

The limitations of this study were identified as:

1. The small sample size did not lend itself to generalization.

2. The sampling procedure was one of convenience.

3. Determination of quality of life using the QLI was done only after implantation. Measurement of quality of life prior to AICD implantation and again six months following implantation may have provided data to assess achievement of expectations at different periods during a chronic illness.

Chapter 2

CONCEPTUAL FRAMEWORK AND REVIEW OF RELATED LITERATURE

Conceptual Framework

Chrisman and Fowler's (1980) systems-in-change model provided the framework for studying quality of life in automatic implantable cardioverter defibrillator (AICD) recipients. Based on the model the AICD recipient is comprised of biologic, personal, and social systems in a continual process of change. These systems interact with the environment along a developmental continuum, striving to achieve, restore, or maintain a state of equilibrium (see Appendix B). Changes within or outside the systems may produce stress that disturbs the tendency of the systems to achieve a state of equilibrium. The status of each system and its interactions influence health, which is defined as a dynamic state of "complete physical, personal, and social well-being, not solely the absence of disease or infirmity" (Chrisman & Fowler, 1980, p. 75).

The systems-in-change model views nursing as a therapeutic process designed to assist in maintaining the equilibrium of the AICD recipient's systems within his/her environment. The nursing process is used to guide the provision of nursing care, with the goals of supporting health and promoting quality of life. The role of nursing

is to support, promote, and maintain equilibrium between the AICD recipient's systems and his/her environment.

As a stressor, tachyarrhythmias produce disequilibrium within the biologic system of the AICD recipient. This stressor is transmitted to the recipient's social and personal systems, where varying degrees of disequilibrium also may occur. By assessing each system and identifying areas of disequilibrium, nursing care plans may be developed to restore the AICD recipient and his/her family to an optimal state of equilibrium.

Review of Related Literature

Quality of Life

There is no generally accepted definition of quality of life found in the literature, nor agreement on which variables to include in its measurement. Individuals assign varying degrees of importance to the life experiences which comprise quality of life, based on their own social, economic, historical, physical, and educational perspectives.

Quality of life was brought to the public's attention during the Johnson Administration in the mid-1960's. "The good life" was described as more than simple material wealth (Ferrans & Powers, 1985). Webster's dictionary (Neufeldt, 1988) defines 'quality' as "any of the features that make something what it is; characteristic element; attribute; the

degree of excellence which a thing possesses." Over the past 20 years quality of life has been measured using a variety of increasingly sophisticated instruments (Cantril, 1965; Campbell, Converse, & Rodgers, 1976; Flanagan, 1978).

Cantril (1965) conceptualized quality of life in terms of life satisfaction. Cantril's subjects were asked to define quality of life based on personal assumptions about what gives life meaning and provides personal satisfaction. The instrument was tested on 20,000 people in 13 different nations. Campbell, Converse, and Rodgers (1976) identified 17 domains of life and obtained responses from subjects in terms of their life satisfaction levels. Flanagan (1978) developed the Quality of Life Scale from the 15 domains revealed by his research. Campbell, Converse, and Rogers (1976), as well as Flanagan (1978), concluded that most people identified five dimensions into which the domains could be placed: (a) physical and material well-being; (b) relations with other people; (c) participation in social, community, and civic activities; (d) personal development and fulfillment; and (e) recreation (Burckhardt, Woods, Schultz, & Ziebarth, 1989).

Ferrans and Powers (1985) found no agreement regarding which aspects of life should be included in measuring quality of life. They found, however, that a growing number of researchers agreed that life satisfaction was the

most important dimension to include in quality of life measurement. Ferrans and Powers sought to create a tool which would address the domains noted by the experts, subjectively evaluate satisfaction with the domains, and measure the importance of each domain to the individual.

Recently, health care professionals who work with chronically ill clients have focused their research on the qualities that give life meaning and satisfaction (Burckhardt, Woods, Schultz, & Ziebarth, 1989). The Quality of Life Scale developed by Flanagan (1978) was used to measure quality of life in clients with diabetes mellitus, colon cancer or colitis requiring an ostomy, osteoarthritis, and rheumatoid arthritis. Burckhardt, Woods, Schultz and Ziebarth concluded that the Quality of Life Scale was conceptually clear, and content-valid, and had potential for use as an outcome measure in chronic illness care. Data from their study indicated that independence directly affected quality of life. Subjects defined independence as including their normal activities of daily living, as well as a sense of not wanting to depend on others. In the discussion of study results, subjective satisfaction with quality of life was related to, but not the same as health status. Definitions for quality of life and health status were not provided.

Padilla et al. (1983) developed an instrument for measuring quality of life of cancer patients. Items focused on those aspects of quality of life relevant to the nursing care of cancer patients. The authors identified three major factors contributing to the quality of life of patients with cancer: (a) psychological well-being, (b) physical well-being, and (c) symptom control. The study measured quality of life in 130 cancer patients and 48 nonpatients. Financial protection was measured by a single question relating to worry over cost of care. All care given was provided free of charge in the study institution.

Quality of life has been measured following coronary artery bypass surgery. Flynn and Frantz (1987) studied the quality of life of 29 subjects using four instruments designed to obtain subjective life satisfaction scores and objective health status information. Despite physical symptoms and reported complications following the surgery, quality of life was enhanced for the majority of patients because of relief of angina. Repeating this study with a larger sample at a longer time after surgery would have provided a more accurate description of quality of life following bypass surgery.

Sirles and Selleck (1989) used King's definition of a social system (King, 1981) to present a general overview of the impact of cardiac disease on the quality of life of the

family. When faced with a life-threatening cardiac illness the family reorganized and stabilized its structure and function as the affected member progressed through the acute, transitional, and rehabilitative phases of recovery. Future nursing research of families facing cardiac disease was suggested to define family health, identify predictors of family strength, and refine tools for family assessment.

Brodsky et al. (1988) were the first authors to research quality of life in AICD recipients. A questionnaire was developed to evaluate the psychological impact of the AICD on the patient and the patient's "caretaker." Results were obtained on psychosocial adaptation from 53 AICD recipients and 52 "caretakers". Specific psychosocial stresses identified by patients were: (a) embarrassment from the firing of the device in a public place, (b) reduced physical activity, (c) thoughts of death, (d) decreased sexual activity, (e) dependency, (f) depression, and (g) memory loss. "Caretakers" were more concerned for the patient's pain, panic, and death. The "caretakers" themselves reported a high incidence (38%) of depression. Better validity and reliability information on this questionnaire was needed. Pre-testing of the tool was not addressed.

Survivors of Sudden Death

Psychological distress in sudden death survivors has been discussed in the literature since the pioneer work by Druss and Kornfeld (1967). This study of ten survivors described insomnia, irritability, and a restriction of activities beyond that recommended by their physicians. Ten patients without cardiac arrest, but treated in the same monitored unit, showed similar emotional problems. Druss and Kornfeld surmised that the presence of heart rhythm disturbances, as opposed to an arrest, may be responsible for the psychological distress.

Much attention has been given to the psychological needs of survivors of sudden death and patients with recurrent ventricular tachycardia without a sudden death event. A large study was conducted by Bergner, Bergner, Hallstrom, Eisenberg, and Cobb (1984), who interviewed 424 survivors a minimum of six months after a sudden death event. The Sickness Impact Profile, a standardized interview that measures sickness-related dysfunction, was used to evaluate health status. Scores were higher (worse) than those of apparently healthy individuals in the same geographical areas. However, the problems were not incapacitating in most cases, and over three-fifths of the survivors who were working prior to the event were able to return to work.

DeBasio and Rodenhausen (1984) noted that patients and their families experience moderate to high levels of stress as a result of the diagnosis of a life-threatening dysrhythmia and accompanying treatment. Psychological implications rather than the physical discomfort of ventricular tachycardia were found to have more profound implications for the family, while patients were surprised by the arrhythmia's impact on lifestyle and personal goals. Patients in this study identified powerlessness and lack of control over many facets of their illness, treatment, and future lifestyle.

The works of Featherston (1988), and Dunnington, Johnson, Finkelmeier, Lyons, and Kehoe (1988) supported these findings. Dunnington and Finkelmeier (1988) conducted a second study which found this population of survivors to have an increase in psychological distress, presumably due to the stress of living with a chronic illness and lifestyle changes that may occur as a direct result of the illness. The study concluded that patients requiring long term medical treatment, those forced to modify work status, and those with more advanced cardiac impairment were at greater risk for emotional consequences, especially when more than one factor was present.

Noel et al. (1986) began to describe the psychological concerns of patients with automatic implantable cardioverter

defibrillators, such as altered body image and self-concept, and feelings of dependency on the device. The authors concluded that patient education and emotional support be provided to assist patients to adjust to the feelings of powerlessness related to the mechanical function of the AICD, fear of its malfunction, discomfort of defibrillation, and potential loss of consciousness.

Miccolo (1988) determined emotional support to be critical for patients undergoing diagnosis and treatment for ventricular dysrhythmias. Dunnington and Finkelmeier (1988) reviewed the research on psychologic responses of sudden cardiac death survivors and described crisis theory as a framework for providing care to these patients and families. This patient group was found to be at risk for developing emotional disequilibrium and crisis. The authors suggested that nurses provide valuable support to patients and families who are temporarily in need of assistance to restore order and balance to their lives.

In the most recent study, Kolar and Dracup (1990) found no differences in psychosocial adjustment between survivors of cardiac arrest and patients with recurrent ventricular tachycardia. They further stated that the cardiac arrest event did not affect patients' psychosocial adjustment any more severely than recurrent ventricular dysrhythmias. Marital status, number of dysrhythmic events, and history of

heart failure were discovered to be predictive of psychosocial adjustment in both groups. This study concurs with the cornerstone work by Druss and Kornfeld (1967).

Automatic Implantable Cardioverter Defibrillators

Much information has been written on the nursing care of patients with AICDs, including indications for the device, identified nursing diagnoses, and outlined pre-surgical and post-surgical care, as well as recommendations for discharge teaching (Cooper, Valladares, & Futterman, 1987; Moser, Crawford, & Thomas, 1988; McCrum & Tyndall, 1989; Veseth-Rogers, 1990). Support groups have begun to be formed at some of the larger institutions as a direct result of these developments. The results of this intervention are emerging in the literature.

Badger and Morris (1989) studied the effect of an eight week support group on six AICD recipients and their spouses. They determined group therapy to be an effective method for promoting positive adjustment to the device. Positive adjustment was suggested by patient self-reported comments and positive trends in role functioning. The limitation of a small population does not lead the reader to generalize, but does suggest future research on a larger scale.

Teplitz, Egenes, and Brask (1990) also described forming an AICD support group for approximately 30 recipients and their families. The need was identified

through the observation of increased anxiety, depression, and feelings of loss of control. Evaluation of this support group is currently in progress.

In a recently published study by Pycha, Calabrese, Gulledge, and Maloney (1990), 42 patients and 38 spouses completed and returned questionnaires designed to elucidate psychosocial adaptation to the AICD. No rationale was given for including spouses in this study. The Beck Depression Inventory, Self-Assessment Anxiety Scale, and Cleveland Clinic AICD Psychosocial Inventory were the tools used to determine adaptation. While results suggested overall successful adaptation to the device, fear and anxiety were associated with the unpredictable nature and timing of the AICD's discharge. Fear of embarrassment, pain, and concern over the cost of the device and related medical expenses also were identified as concerns. All patients and spouses agreed that the device allowed them to return to an active lifestyle.

In summary, quality of life has been discussed in the literature since the mid-1960's. Quality of life has been conceptualized for this study using Chrisman and Fowler's systems-in-change model (Chrisman & Fowler, 1980). Increasingly sophisticated instruments have been used to capture quality of life in terms of life satisfaction. Quality of life has been studied in several patient

populations with chronic illnesses. Several authors (Pycha, Calabrese, Gulledge, & Maloney, 1990; Teplitz, Egenes, Brask, 1990; Badger & Morris, 1989) have explored the psychological effects of sudden cardiac death and AICD implantation. However, only recently has research emerged linking these psychological aspects with quality of life. Therefore, this study was performed to explore quality of life in AICD recipients and to contribute to the body of knowledge on quality of life as it relates to chronic illness.

Chapter 3

METHOD

Research Design

This was an exploratory study of the perceived quality of life of automatic implantable cardioverter defibrillator (AICD) recipients. Both survey and interview techniques were used for collecting data. Research in this area has only recently begun to emerge, therefore the researcher explored the perceived quality of life of a select group of AICD recipients. No attempt was made to manipulate variables or establish causal relationships.

Subjects

The subjects who participated in this study were a convenience sample of 37 AICD recipients. These patients were part of a population accessible to the researcher through referrals. These were patients who chose to have their cardiac arrhythmias managed by a Northern California cardiology group before being contacted to participate in the study. A list of AICD recipients was obtained from the physician group. Patients' medical records were screened to meet the following inclusion criteria: (a) being over 40 years of age; (b) being able to speak, read, and write in English; and (c) having had an AICD for at least one month.

Patients qualifying as subjects were contacted by mail, requested to complete an enclosed questionnaire, and return

it to the researcher in a self-addressed stamped envelope. Those patients returning completed questionnaires were the subjects for this study.

Instrument

The Quality of Life Index (QLI) by Ferrans and Powers was the instrument used to measure quality of life (see Appendix A). The questionnaire consisted of two sections, one measuring satisfaction with various domains of life, the other measuring the importance of the domain to the subject. QLI scores were determined by adjusting satisfaction responses for the importance responses. The adjusted QLI scores reflected not only satisfaction, but also how much an individual valued each domain (Ferrans & Powers, 1985). Subjects responded to questions on a six-point Likert type scale ranging from "very satisfied" to "very dissatisfied" for 36 satisfaction items, and "very important" to "very unimportant" for 36 importance items. An overall QLI score was obtained for each subject. Scores also were calculated for the following subscales: (a) health and functioning, (b) socioeconomic, (c) psychological/spiritual, and (d) family.

Data Collection Procedures

Permission for this study was obtained from the Human Subjects Institutional Review Board at San Jose State University (see Appendices C and D). An additional letter

of authorization was obtained from the cardiology medical group at the sample site (see Appendix E). A letter of consent (see Appendix F), demographic survey (see Appendix G), and Quality of Life Index questionnaire were mailed to 60 patients. An Experimental Subjects Bill of Rights (see Appendix H) also was included to assure participants anonymity. This bill informed them of their right to withdraw from participation in the study at any time.

A follow-up telephone call was made to potential subjects who had not returned their questionnaires, approximately two weeks following the mailing. At that time patients were asked if they intended to complete the questionnaire, and a further explanation of the study and review of the rights of human subjects were given. Thirty-seven (61.7%) of the 60 potential subjects responded by returning a completed questionnaire.

Completed questionnaires were coded by the researcher when received. At the end of data collection, scores were tabulated and statistical analyses were completed by computer using an IBM statistical package SPSS/PC+.

Seven of the 37 subjects were chosen randomly for telephone interviews. Numbers were assigned to each subject and placed in a hat. The first seven numbers drawn from the hat became the subjects to be interviewed. These seven subjects were asked to describe their perceptions of life

style changes occurring as a result of AICD implantation. Subjects were asked the following two questions:

1. What was the most significant change in your life since the defibrillator was implanted?

2. Who, other than yourself, has been most affected by this change?

Descriptive data obtained from these conversations are presented along with the findings in Chapter 4.

In summary, this research study was designed to explore quality of life of AICD recipients using a convenience sample referred to the researcher by professional contacts. A mailed questionnaire was used to collect data. Quality of life was measured via questions addressing the health and functioning of AICD recipients, as well as their socioeconomic, psychological/spiritual, and family issues. Telephone interviews were conducted to gain additional information regarding significant lifestyle changes.

Chapter 4

FINDINGS

This chapter describes the perceived quality of life of 37 automatic implantable cardioverter defibrillator (AICD) recipients as measured by the Quality of Life Index (QLI). Data from this study were analyzed to determine: (a) if correlations existed between the scores on the QLI and length of time since AICD implantation, and (b) if correlations existed between the scores on the QLI and number of converting shocks delivered by the AICD. Data from 37 questionnaires were analyzed. The IBM statistical package SPSS/PC+ was used to process the data.

The results of this study are presented in the following order: (a) demographic profile of the subjects; (b) description of quality of life based on the QLI; (c) the relationship between length of time since AICD implantation and QLI scores; (d) the relationship between the number of converting shocks delivered and QLI scores; and (e) description of lifestyle changes occurring as a result of AICD implantation.

Demographic Profile of the Subjects

Demographic characteristics of the subjects are presented in Table 1. The study sample consisted of 32 men and 5 women ranging in age from 42 to 78 years, with the mean age being 66.62. The length of time since implantation

Table 1

Demographic Findings

Subject #	Age	Sex	Number of Shocks	Time since Implantation (in months)
1	58	M	5	12
2	62	M	0	12
3	67	F	0	24
4	73	M	0	15
5	69	M	0	15
6	63	M	0	17
7	67	F	0	20
8	71	M	5	6
9	63	M	5	18
10	74	M	0	12
11	60	M	0	14
12	60	M	1	17
13	63	M	0	12
14	64	M	1	10
15	66	M	6	7
16	70	M	0	11
17	69	M	0	9
18	63	M	0	9
19	70	M	0	10

Table 1 (Continued)

Demographic Findings

Subject #	Age	Sex	Number of Shocks	Time since Implantation (in months)
20	68	M	0	6
21	69	M	0	9
22	69	M	0	5
23	75	M	1	13
24	42	M	0	7
25	72	M	0	8
26	60	M	2	5
27	77	F	15	8
28	72	M	0	4
29	66	M	1	7
30	69	M	8	12
31	56	M	?	18
32	62	F	0	23
33	77	M	0	15
34	78	M	?	9
35	73	F	3	21
36	71	M	30	18
37	57	M	2	12

of the AICD ranged from 4 to 24 months, with a mean of 12.27 months. The frequency of converting shocks delivered ranged from 0 shocks to a maximum of 30 shocks, with a mean of 2.43. Twenty-one recipients (56.8%) reported receiving no shocks, while eight (21.6%) reported receiving five or more shocks. Two recipients (5.4%) failed to report the number of converting shocks received.

Quality of Life Based on the QLI

The QLI was used to calculate quality of life by determining an overall score for each subject. Also, scores were calculated for each subject on each of the following QLI subscales: (a) health and functioning, (b) socioeconomic, (c) psychological/spiritual, and (d) family. The QLI scores for each subject are presented in Table 2.

The range possible for each QLI score was 0 to 30, with 0 representing the worst possible quality of life, and 30 being the best. The overall QLI scores in the study population ranged from 12.29 to 29.68 with a mean of 22.60. Most (75.7%) of the respondents had overall QLI scores of 20 or greater.

The health and functioning subscale measured the patient's perception of quality of health, health care, chest pain, shortness of breath, energy, physical independence, amount of control over life, potential for a

Table 2

Quality Of Life Index Scores

SUBJECT #	OVERALL QLI	HEALTH/ FUNCTION	SOCIO/ ECON	PSYCHO/ SPIRIT	FAMILY
1	23.00	22.78	24.25	21.71	23.63
2	27.27	25.84	28.94	27.93	28.50
3	22.22	20.97	23.57	20.21	30.00
4	26.75	26.56	28.29	25.50	27.00
5	28.17	27.53	29.64	27.00	30.00
6	15.20	15.16	17.06	20.14	3.00
7	19.72	13.13	26.57	22.07	30.00
8	15.64	8.80	21.43	16.29	30.00
9	20.43	19.75	22.25	20.43	19.50
10	20.42	16.46	26.57	19.29	25.50
11	26.74	27.38	28.50	24.86	24.00
12	24.25	25.06	23.06	22.75	27.00
13	21.40	19.50	23.88	22.29	22.50
14	16.57	11.56	18.93	18.00	30.00
15	23.16	24.03	20.44	24.00	23.63
16	29.68	30.00	29.29	29.14	30.00
17	23.68	24.18	23.14	23.14	24.00
18	28.55	28.18	27.38	30.00	30.00
19	25.07	24.69	27.14	23.64	25.50

Table 2 (Continued)

Quality Of Life Index Scores

SUBJECT #	OVERALL QLI	HEALTH/ FUNCTION	SOCIO/ ECON	PSYCHO/ SPIRIT	FAMILY
20	24.34	22.41	24.75	25.07	30.00
21	25.32	22.06	28.57	27.71	28.50
22	29.14	28.13	30.00	30.00	30.00
23	22.41	20.47	24.00	24.93	22.50
24	26.21	26.63	26.06	23.29	30.00
25	23.25	18.75	24.64	28.29	30.00
26	12.29	7.53	18.38	8.64	25.50
27	20.97	13.39	27.00	26.64	27.00
28	22.56	21.38	24.43	20.86	27.00
29	26.64	26.21	24.70	28.58	28.00
30	18.96	15.00	21.50	22.07	26.00
31	21.81	19.50	22.69	23.14	27.00
32	26.78	25.32	28.50	27.50	28.50
33	23.64	23.84	21.38	22.14	30.00
34	28.43	28.27	29.06	27.50	29.38
35	13.38	12.38	14.08	13.00	24.00
36	18.03	11.00	25.00	22.50	24.38
37	14.26	13.34	16.29	10.14	24.00

long life, sex life, ability to meet family responsibilities, usefulness to others, amount of stress or worries, leisure activities, travel, potential for a happy old age or retirement, and life changes resulting from the heart condition. Health and functioning subscale scores ranged from 7.53 to 30.00 with a mean of 20.73.

It should be noted that health was valued as "very important" by 94.6% of the respondents. The majority of respondents (75.7%) were satisfied with their health. Nearly all (89.2%) of respondents were "moderately" to "very satisfied" with the health care they received. The entire sample valued health care as important. The most frequently omitted response in this subscale was about sexual satisfaction.

Socioeconomic subscale scores ranged from 14.08 to 30.00 with a mean of 24.36. Questions in this domain focused on friends, emotional support from others, home, neighborhood, standard of living, job, education, and financial independence. The entire study population was "moderately" to "very satisfied" with the emotional support they received from others, which 97.2% valued as important. All except one respondent valued financial independence as "moderately" to "very important," yet satisfaction responses for this domain

varied from "very dissatisfied" to "very satisfied." Responses aimed at job satisfaction and importance indicated 70% of subjects were retired.

The psychological/spiritual subscale included questions related to peace of mind, faith in God, achieving personal goals, happiness, life satisfaction, personal appearance, and self concept. Scores ranged from 8.64 to 30.00, with a mean of 22.98. Peace of mind was valued as "very important" by 94.6% of the study population, with the remainder placing "moderate" importance on the domain. Over three-fourths (78.1%) of the population were satisfied with their peace of mind. All but two (94.5%) of the sample claimed to be satisfied with life in general, which was valued as important by the entire sample.

The family subscale was the smallest measure on the QLI. Items relating to family's health, children, family's happiness, and relationship with spouse or significant other were included. The range for the family subscale scores was 3.00 to 30.00, with a mean of 26.36. Most respondents (94.0%) were satisfied with their relationship with spouse or significant other.

All but one (97.1%) placed "moderate" to "very important" values on this domain. All subjects placed "moderate" to "very important" values on the domains of family health, family happiness, and children. Satisfaction values for these domains were more variable.

Relationship Between Length of Time Since AICD Implantation and QLI Scores

Correlation coefficients were computed between length of time since implantation and overall QLI scores, as well as scores for health and functioning, socioeconomic, psychological/spiritual, and family subscales. No significant relationship was found between any index and length of time since implantation (see Table 3). The family subscale, however, did show the strongest correlation (r = -.23).

Table 3

Correlation Between Time Since Implantation and Quality Of Life Index

Correlations:	QLI	HEALTH	SOCIO/ ECON	PSYCHO/ SPIRIT	FAMILY
LENGTH OF TIME SINCE IMPLANTATION	-.12	-.06	-.09	-.11	-.23

N = 35

Relationship Between Number of Shocks and QLI Scores

Correlation coefficients were computed between number of converting shocks delivered and overall QLI scores. Also, correlation coefficients were computed between number of converting shocks delivered and scores for health and functioning, socioeconomic, psychological/spiritual, and family subscales. A low correlation (r = -.31) existed between overall QLI scores and number of shocks. A moderate correlation (r = -.44) existed between the health and functioning subscale scores and number of shocks delivered (see Table 4).

TABLE 4

Correlation Between Number Of Shocks and

Quality Of Life Index

Correlations:	QLI	HEALTH	SOCIO/ ECON	PSYCHO/ SPIRIT	FAMILY
NUMBER OF SHOCKS DELIVERED	-.31	-.44*	-.09	-.08	-.10

N = 35

* $p \leq .01$ (one-tail)

Description of Lifestyle Changes

Seven subjects were selected randomly for telephone interviews. Interviewees ranged in age from 62 to 78 years; six were male. When asked to state the most significant change occurring since AICD implantation, the most common response (n = 3) was inability to drive. One subject claimed he made no important changes in his life. Two male subjects stated forced retirement was the most important change, and another male subject feared traveling beyond the immediate area where his physician practices.

Four male subjects identified their spouses as most affected by subsequent changes in each subject's lifestyle. The one female subject cared for an 11 year old grandson, and claimed he was greatly affected by her lifestyle changes, as well as her significant lack of energy. The remaining two subjects stated their children were greatly affected by the need to accept responsibilities resulting from the changes in lifestyle brought on by AICD implantation.

In summary, these research findings described the perceived quality of life of AICD recipients. Using the QLI, quality of life was correlated with length of

time since AICD implantation and the number of converting shocks delivered. Automatic implantable cardioverter defibrillator implantation led to significant lifestyle changes as revealed by seven telephone interviews. Other than the subjects, spouses were identified as most affected by these lifestyle changes.

Chapter 5

CONCLUSIONS AND RECOMMENDATIONS

Discussion

During the past ten years the automatic implantable cardioverter defibrillator (AICD) has been useful in reducing the incidence of sudden cardiac death (Moser, Crawford, & Thomas, 1988). Only recently has quality of life been studied in this population. This study sought to: (a) describe the quality of life of AICD recipients using the Quality of Life Index (QLI); (b) determine if correlations existed between length of time since AICD implantation and QLI scores; and (c) determine if correlations existed between the number of shocks delivered by the AICD and QLI scores.

When the quality of life of AICD recipients was described using the systems-in-change conceptual framework, three relationships became evident. First, sudden cardiac death and the resulting treatment with the AICD produced stress within the biologic system, which disturbed the system's ability to achieve equilibrium. Second, results obtained in this small population indicated that attempts were made to restore equilibrium most frequently via relationships within the social system. And finally, the high scores obtained in the family subscale indicated family relationships provided the greatest life satisfaction to

this population. Based on the findings, it is logical to assume that the family provided the greatest support system to this group of subjects.

The mean overall QLI score was 22.60 for the subjects of this study. The range possible for each QLI score was 0 to 30 with higher scores indicating a better quality of life. The mean overall QLI score would seem to indicate AICD recipients were satisfied with their overall quality of life after AICD implantation. Greatest satisfaction was indicated in the family subscale, with a mean score of 26.36. Although quality of life has been measured in this population with fairly positive results, no conclusion may be drawn that the degree of quality of life an individual possesses is a result of AICD implantation since quality of life was not measured prior to AICD implantation.

The lowest satisfaction score obtained was in the health and functioning subscale, with a mean of 20.73. This finding does not support previous research. Other studies have demonstrated psychological concerns, versus a decline in health and functioning, as the most commonly identified problem following AICD implantation (Debasio & Rodenhausen, 1984). An explanation for this difference may relate to the small sample size (n = 37). Additionally, no data were gathered regarding the subject's concomitant illnesses, or level of health and functioning prior to AICD implantation.

It was expected that the AICD recipient's quality of life would increase as length of time since AICD implantation increased. No significant correlation was found between any QLI score and length of time since AICD implantation. It should be noted, however, all five *r* values were negative, which, if large enough to be statistically significant, would indicate the opposite of what was expected. Since there was no data prior to implantation, it cannot be determined whether or not the surgical procedure had a measurable effect on quality of life. This relationship is important to determine in that the maximum life expectancy of the AICD battery is three years. In other words, patients require surgical battery replacement every three years.

It was expected that the number of shocks an AICD recipient received would adversely affect his/her perceived quality of life. A moderate correlation was found between the health and functioning subscale score and the number of shocks delivered. A low correlation was found between the overall QLI score and the number of shocks delivered. Therefore, statistical analysis indicated that although the AICD provides a degree of peace of mind, the shocks have a negative effect on the physical well being of the individual, and on his/her overall perceived quality of life.

Telephone interviews identified spouses and children as most affected by lifestyle changes occurring as a result of the AICD. All lifestyle changes identified in the interviews decreased the AICD recipient's independence. Interventions focused on providing support and education to the patient-family unit may assist in adaptation to the AICD. Support groups have been found to be effective in reducing stress among patients and families with a variety of problems and in facilitating adjustment to illness. This has been successfully reported in the literature with the use of support groups after AICD implantation (Teplitz, Egenes, & Brask, 1990; Pycha, Calabrese, Gulledge, & Maloney, 1990; Badger & Morris, 1989).

Limitations

The major limitations of this study were: (a) small sample size, (b) convenience sampling, (c) self-administered questionnaire, and (d) lack of control over possible intervening variables. The small sample size may prevent results from being generalized to a larger population. Economic classes and ethnic groups were not distinguished by the questionnaire with this convenience sample. The influence of the spouse or other family members may have had an affect on the results, or even determined whether or not the prospective subject would respond to the

self-administered questionnaire. The subjects of this study may have had concomitant illnesses which affected their quality of life more than AICD implantation.

Another limitation of the study may exist with the use of the Quality of Life Index. No definition of the final score was provided with the tool. The application of a Likert type scale to the final score would provide definition and guide the user to more adequately describe quality of life in patient groups. For example, a score of 0-5 would represent "very poor," 6-10 "somewhat poor," 11-15 "fair," 16-20 "good," 21-25 "very good," and 26-30 "excellent" quality of life. Even this solution would be incomplete. The QLI implies interval level data with a possible QLI score falling between 0 and 30. Yet there is no evidence that one score is equidistant in reality from the next score. That is, the QLI indicates little, if any, more than direction. Therefore, the researcher does not know how much greater a QLI score of 25 is compared to 24, only that it is greater.

Recommendations

Recommendations for further research are: (a) use of a larger sample distinguishing different ethnic and socioeconomic backgrounds, (b) measurement of perceived quality of life before and after AICD implantation, (c) use of other instruments in conjunction with the QLI for greater

validity testing, and (d) controlling for the possible effect of concomitant illness by separating subjects into illness groups using the New York Heart Association's Functional Classification System, (Underhill, Woods, Sivakajan, & Halpenny, 1982, p. 152).

In terms of nursing intervention the most important recommendation of this study is to include quality of life determinations of the AICD recipient's family members. This information can be used to make comparisons between the perceived quality of life of AICD recipients and their respective family members. Two findings indicate the need to study the effects of AICD implantation upon the family members of AICD recipients. The highest satisfaction scores were obtained in the family subscale. Also, family members were identified as the most affected by the AICD recipient, other than themselves. A support group for AICD recipients and their families may be an effective method of providing education and emotional support. Support groups for cardiac surgery patients and their families have been a method for identifying perceived health teaching needs and providing a supportive environment for post-operative adjustment (Teplitz, Egenes, & Brask, 1990). Studying the effects of such a group on the AICD population would provide nurses with information to help patients and families successfully adapt to this treatment.

The AICD is a life-saving device that will be implanted with increasing frequency in patients with cardiac arrhythmias. This study has provided knowledge about the quality of life of AICD recipients which is necessary for health care providers to support patients and their families in making the appropriate choices regarding treatment, and in adjusting successfully to the chosen therapy.

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APPENDICES

APPENDIX A

Quality of Life Index

APPENDIX B

Systems-In-Change Conceptual Framework

APPENDIX C

Institutional Review Board-Human Subjects

Approval Letter

San Jose State University

SJSU SAN JOSE STATE UNIVERSITY

A campus of The California State University

Office of the Academic Vice President • Associate Academic Vice President • Graduate Studies and Research
One Washington Square • San Jose, California 95192-0025 • 408/924-2480

To: Debra L. Deis, Nursing
1030 Cedar Lane Court
Danville, CA 94526

From: Charles R. Bolz
Office of Graduate Studies and Research

Date: April 9, 1991

The Human Subjects Institutional Review Board has reviewed and approved your request for exemption from Human Subjects Review for the proposed study entitled:

"Quality of Life in Automatic Implantable Cardioverter Defibrillator Recipients"

You may proceed with this study without further review by the Human Subjects Institutional Review Board.

I do caution you that Federal and State statutes and University policy require investigators conducting research under exempt categories to be knowledgeable of and comply with Federal and State regulations for the protection of human subjects in research. This includes providing necessary information to enable people to make an informed decision regarding participation in your study. Further, whenever people participate in your research as human subjects, they should be appropriately protected from risk. This includes the protection of the confidentiality of all data that may be collected from the subjects. If at any time a subject becomes injured or complains of injury, you must notify Dr. Serena Stanford immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

Please also be advised when people participate in your research as human subjects, each subject needs to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate or withdrawal will not affect any services the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact Dr. Stanford or me at (408) 924-2480.

cc: Terry W. Miller, RN, D.N.Sc.

APPENDIX D

Institutional Review Board-Human Subjects

Amended Approval Letter

SAN JOSE STATE UNIVERSITY

SJSU SAN JOSE STATE UNIVERSITY

A campus of The California State University

Office of the Academic Vice President • *Associate Academic Vice President* • *Graduate Studies and Research*
One Washington Square • San José, California 95192-0025 • 408/924-2480

To: Debra L. Deis, Nursing
1030 Cedar Lane Court
Danville, CA 94526

From: Serena W. Stanford Serena W. Stanford
AAVP, Graduate Studies and Research

Date: June 24, 1991

The Human Subjects Institutional Review Board has reviewed and approved your request for exemption from Human Subjects Review for the proposed study entitled:

> "Quality of Life in Automatic Implantable Cardioverter Defibrillator Recipients (as amended by your request for minor changes dated June 17, 1991)"

You may proceed with this study without further review by the Human Subjects Institutional Review Board.

I do caution you that Federal and State statutes and University policy require investigators conducting research under exempt categories to be knowledgeable of and comply with Federal and State regulations for the protection of human subjects in research. This includes providing necessary information to enable people to make an informed decision regarding participation in your study. Further, whenever people participate in your research as human subjects, they should be appropriately protected from risk. This includes the protection of the confidentiality of all data that may be collected from the subjects. If at any time a subject becomes injured or complains of injury, you must notify Dr. Serena Stanford immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

Please also be advised when people participate in your research as human subjects, each subject needs to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate or withdrawal will not affect any services the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact me at (408) 924-2480.

CC: Terry W. Miller, RN, D.N.Sc.

APPENDIX E

Letter of Approval From Sample Site

Cardiovascular Medicine, Coronary Interventions and Cardiac Arrhythmias
A Partnership of Incorporated Medical Groups
770 Welch Road, Suite 100 • Palo Alto, California 94304
(415) 327-7231

John B. Simpson, M.D.
Edward T. Anderson, M.D.
Dennis J. Sheehan, M.D.
Bruce J. McAuley, M.D.
Matthew R. Selmon, M.D.
Gregory C. Robertson, M.D.

Roger A. Winkle, M.D.
R Hardwin Mead, M.D.
Michael A. Ruder, M.D.
Nellis A. Smith, M.D.
Tomoki Hinohara, M.D.

February 15, 1991

RE: DEIS, Debra

TO WHOM IT MAY CONCERN:

This letter is to confirm the fact that we have given permission for Ms. Debra Deis to interview our patients, and to have them complete a questionnaire as part of her investigation into the quality of life of automatic implantable cardioverter defibrillator patients. We have read through the protocol and the questionnaire which she proposes to use with our patients and have absolutely no objections to her proceeding with the study as she plans.

Please feel free to contact me at the address above should you have any further questions regarding this.

Sincerely,

R. Hardwin Mead

R. Hardwin Mead, M.D.

RHM:mms

APPENDIX F

Letter of Consent

SJSU SAN JOSE STATE UNIVERSITY

A campus of The California State University

School of the Applied Arts and Sciences • Department of Nursing
One Washington Square • San José, California 95192-0057 • 408/924-3130

June 6, 1991

Dear Patient:

I need your help in conducting a study of the effects of the Automatic Implantable Cardioverter Defibrillator (AICD) on quality of life. The results of this study should assist in the development of programs aimed at increasing quality of life. Attached is a questionnaire asking about your satisfaction with various areas of your life, and the importance of each area. Would you please spend 15 minutes to complete the form and mail it to me within the next two weeks? I have included a self-addressed, stamped envelope for your convenience.

You should be clear that your participation in this study is voluntary. Also, any information that could be identified with you will remain anonymous and could only be disclosed as required by law.

If you have any questions about this study, I would be happy to talk with you. I can be reached at (415)743-1419. My graduate advisor is Terry Miller, RN. He is also available to answer questions and can be reached at (408)924-3171. I hope that you will find the time to help us understand better how the AICD impacts quality of life.

Sincerely,

Debra L. Deis

Debra L. Deis, RN
Graduate Student

APPENDIX G

Demographic Survey

DEMOGRAPHIC SURVEY

1. Your age? _____
2. Your sex? _____
3. How long has your AICD been implanted? _____
4. How many shocks has it delivered? _____

APPENDIX H

Experimental Subjects Bill of Rights

EXPERIMENTAL SUBJECTS
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,
2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4) To be told if I can expect any benefit from participating and, if so, what the benefit might be,
5) To be told the other choices I have and how they may be better or worse than being in the study,
6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7) To be told what sort of medical treatment is available if any complications arise,
8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9) To receive a copy of the signed and dated consent form,
10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher. In addition, I may contact the Human Subjects Institutional Review Board, which is concerned with protection of volunteers in research projects. I may reach the committee by calling: (408)924-1438 from 8:00 AM to 5:00 PM Monday through Friday, or by writing to the Human Subjects Institutional Review Board, San Jose State University Foundation, One Washington Square, San Jose, CA 95192-0139.

APPENDIX I

Permission To Use The Quality of Life Index

UIC
The University of Illinois at Chicago

Department of Medical-Surgical Nursing (M/C 802)
College of Nursing
845 South Damen Avenue, 7th Floor
Box 6998, Chicago, Illinois 60680
(312) 996-7900

November 7, 1990

Ms. Debra L. Deis
1030 Cedar Lane Court
Danville, CA 94526

Dear Ms. Deis:

Thank you for your interest in the Quality of Life Index (QLI). I have enclosed the cardiac version of the QLI and the computer program for calculating scores. I also have included a list of the weighted items that are used for each of four subscales: health and functioning, socioeconomic, psychological/spiritual, and family, as well as the computer commands used to calculate the subscale scores. The same steps are used to calculate subscale scores and overall scores.

You have my permission to use the QLI for your study. There is no charge for use of the QLI. However, if you do use the QLI for your research and publish an article(s) reporting the findings, I would appreciate it very much if you would send me a copy. Such reports are extremely important to me.

If I can be of further assistance, please do not hesitate to contact me. I wish you much success with your research.

Sincerely,

Carol Ferrans

Carol Estwing Ferrans, PhD, RN
Assistant Professor